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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION
09/897,476	07/03/2001	Edoardo Camenzind	017753-148	2491
7590 05/30/2002				
Norman H. Stepno, Esquire BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404				
EXAMINER				
RAMANA, ANURADHA				
ART UNIT		PAPER NUMBER		
3751				

DATE MAILED: 05/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,476

Applicant(s)

CAMENZIND ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 1,4,13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

New formal drawings are required in this application because the drawings provided do not clearly illustrate the invention.

The drawings are also objected to because of the following informalities.

Elements 8 and 10 appear to be reversed in Figure 4 from their original representation in Figure 3. Appropriate correction is required.

Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because of the use of legal phraseology. Applicant is reminded of the proper language and format for an abstract of the disclosure. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. A patent abstract is a brief technical disclosure of the patent and should include that which is new in the art to which the invention pertains.

The disclosure is objected to because of the following informalities. On page 41, line 5: it appears that arm "7" should be arm "140."

Claims 1, 4, and 13 are objected to because of the following informalities.

Claim 1 recites "and dispensing means" which should be "and a dispenser means" to be consistent with dependent claims which recite "dispenser means."

Claim 4 contains the extraneous word "any" before "Claim 1, ...".

Claim 13 requires insertion of - - "in a" - - after "dispenser means" and before "radial fashion.."

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation, "cutting or perforating means." There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation, "the channels being open in a direction opposite to an axis of the device." It is unclear what is meant by "a direction opposite to an axis of the device."

Claim 13 recites the limitation "wherein the balloon..." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Auth (US 4,445,509) in view of Lin et al. (US 5,792,105).

Regarding claims 1 and 2, Auth discloses controllable removal of abnormal deposits from organic structures (col. 2, lines 63-68) by passing a cutting tool 1 mounted at the end of a torque-transmitting hollow, tubular drive shaft or "entry means" 2 surrounded by a catheter 3 (Figure 1; col. 2, lines 21-25, lines 34-35 and lines 51-52) wherein the entry means 2 is axially translatable with respect to catheter 3 (col. 5, lines 56-58). Cutting tool 1 of Auth has a plurality of cutting blades 14 (col. 3, lines 16-18; col. 6, line 41; Figure 5; and Figure 6). Further, Auth discloses

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fluid ports 25 and 15 to inject chemicals useful for dissolving emboli (col. 7, lines 60-63; Figure 5; and Figure 6).

Auth does not disclose a dispensing means to place a composition in contact with the "blind openings." Examiner notes that the Auth cutting tool 1 makes "blind openings" since the cutting blade 14 of cutting tool 1 has a sharp tip (Figure 3).

Lin et al. disclose a multi-lumen medication dispensing means or balloon catheter 10 with an inner balloon wall 12, an outer balloon wall 14 and dividers 17 which define channels or conduits 16 therebetween. Each channel 16 terminates in an outlet 20 on the outer balloon wall 14 through which medication 19 is delivered (Figure 1 and col. 3, lines 21-31). Lin et al. further disclose that it is known to utilize inflatable medical devices such as balloon catheters to enlarge the cross section of an artery and also dispense medication to the site that has been forcibly expanded (col. 1, lines 11-27).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time was made to replace the catheter 3 of Auth with a medication dispensing balloon catheter 10 as taught by Lin et al. to obtain the Auth-Lin apparatus to provide for simultaneous dispensing of medication along with removal of abnormal deposits from the inner wall of an artery or a treatment site.

Regarding claim 8, the dispensing means is radially extensible relative to an axial direction in the Auth-Lin apparatus.

Regarding claims 10 and 11, the dispensing means of the Auth-Lin apparatus has channels 16 and is closed by outer balloon wall 14 containing openings 20. Further, dispensing balloon catheter 10 surrounds entry means 2 in the Auth-Lin apparatus.

Regarding claims 12 and 13, as previously discussed, entry means 2 is axially translatable within the dispensing balloon catheter 10 of the Auth-Lin apparatus.

Regarding claim 14, the functional statement of intended use has been carefully considered but is deemed not to impose any structure on the claim distinguishable over the Auth-Lin apparatus.

Regarding claim 15, a catheter is a well-known tubular device whose selection is deemed to be well within the level of ordinary skill in the art based on the intended use of the device.

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Claims 3-7 rejected under 35 U.S.C. 103(a) as being unpatentable over Auth (US 4,445,509) in view of Lin et al. (US 5,792,105), as applied to claims 1-2, further in view of Lemelson et al. (US 5,728,123).

Regarding claims 3 and 4, Auth does not disclose a radially expandable entry means.

Lemelson et al. disclose a catheter 9 with a torque-transmitting tubular structure 10 having a radially expandable balloon or "inflatable chamber" 11 secured around its distal end with blade support arms 16 having cutting blades 18 whereby expansion of balloon 11 forces the blade support arms 16 radially outward to operatively extend the cutting blades 18 (col. 3, lines 38-45; col. 4, lines 1-4 and lines 12-14; Figure 1A; and Figure 1B). Lemelson et al. disclose that catheter 9 overcomes the problems associated with a typical artherectomy catheter where the cutting blades extend to the desired cutting radius while the artherectomy catheter is being maneuvered to the correct position ("treatment site") resulting in the risk of inadvertent injury as well as an encumbered passage of the artherectomy catheter (col. 2, lines 37-42).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a torque-transmitting tubular structure 10 as taught by Lemelson in the Auth-Lin apparatus wherein the cutting blades extend to the desired cutting radius, to provide for operative extension of cutting blades 14 to allow for unencumbered passage of cutting tool 1 of the Auth-Lin apparatus to the treatment site with the avoidance of inadvertent injury.

Regarding claim 5, Lemelson et al. further disclose that cutting blades 18 may be directly cemented or molded integral with the walls of the balloon or "inflatable chamber" 11 (col. 5, lines 35-36).

Regarding claims 6 and 7, Lemelson et al. disclose blade support arms 16 carrying cutting blades 18 (col. 3, lines 38-45; col. 4, lines 1-4 and lines 12-14; Figure 1A; and Figure 1B). Further, Lemelson et al. disclose an embodiment wherein the blade support arms 27 are attached to tubular structure 20 by a conduit or "tube" 25 which extends from tube 20 into the balloon or "inflatable chamber" 22 (col. 4, lines 24-32).

Regarding claim 16, the functional statement of intended use in a human or animal body has been carefully considered along with the other limitations but is deemed not to impose any

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structure on the claim distinguishable over the Auth-Lin apparatus in light of the discussion for claims 1, 2, 3, 11 and 13.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Bacher et al. (US 5,599,307) : Col. 4 lines 10-27 and col. 8, lines 3-8.

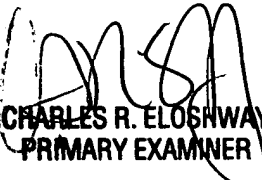
Wang (US 5,254,089): Col. 3, lines 55-65.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached on 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (703) 308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0975.

AR
May 24, 2002


CHARLES R. ELOSKWAY
PRIMARY EXAMINER